UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

KARON-JAHLIL WILLIAMS	*	CIVIL ACTION NO. 6:14-cv-03354-SMH-MLH
Plaintiff,	*	JUDGE HICKS
Versus	*	MAGISTRATE HORNSBY
JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON, JANSSEN RESEARCH AND DEVELOPMENT, LLC	*	
Defendant.	*	

* *

MEMORANDUM IN SUPPORT
OF MOTION FOR SUMMARY JUDGMENT

MAY IT PLEASE THE COURT:

Defendants, Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research and Development, LLC (hereinafter "Defendants"), submit this memorandum in support of their motion for summary judgment. This Motion should be granted because Plaintiff has failed to produce any evidence – fact or expert – supporting his claims in this case.

In his lawsuit, Plaintiff claims that he developed gynecomastia (abnormal enlargement of breast tissue) from the use of the prescription medicine Risperdal.® At his deposition, however, Plaintiff could not articulate the medical condition he claims he suffered, what medicine caused it, when he took this medicine, or when his injuries manifested. Since that time, Plaintiff's expert disclosure deadline (which has been extended twice) has passed and Plaintiff has failed to disclose any experts at all.

Plaintiff's claims are governed by the Louisiana Product Liability Act, LA. REV. STAT. § 9:2800.51, *et seq.* ("LPLA"), and should be dismissed for two reasons: First, the LPLA requires expert evidence to prove medical causation and Plaintiff has failed to produce such evidence. Second, even if there were evidence of causation, Plaintiff has produced no evidence supporting his claim that Risperdal® is defective within the meaning of the LPLA. Accordingly, Plaintiff's Complaint should be dismissed.

I. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

On December 8, 2014, Plaintiff Karon-Jahlil Williams filed the instant Complaint, claiming that he was prescribed Risperdal® (risperidone), Risperdal Consta® (a long-acting injectable form of risperidone), Invega® (paliperidone) and/or Risperidone by various healthcare providers. (Rec. Doc. 1, at ¶ 6). Plaintiff alleges that he developed gynecomastia (enlargement of the breasts) as a result of using the medicine (Id., at ¶ 7). However, Plaintiff has no first-hand knowledge of the specifics regarding the allegations set forth in his Complaint. Plaintiff testified as follows:

Q: What's your understanding of the reason for the lawsuit?

A: Because of the medicine.

Q: Okay, go ahead.

A: Which gave me – I can't pronounce it.

Q: Gynecomastia?

A: Yes, sir.

Q: And that's enlargement of the breasts?

A: Yes.

Q: When did you take the medicine?

A: I don't recall.

Q: What's the name of the medicine?

A: I don't remember.[1]

* * *

Q: Do you know what the medicine Risperdal is? Does that sound familiar to you?

A: Yes.

Q: And what do you know about that?

A: I know I took it when I was younger.

Q: Do you know when?

A: No.

Q: Do you know which doctor prescribed it?

A: No.

Q: Do you know why you were taking it?

A: No.

Q: Do you know how long you took it?

A: No.

Q: Do you know how old you were?

A: No.[2]

Notwithstanding the lack of information from the plaintiff, his medical records demonstrate that he was prescribed Risperdal by Dr. Rita Agarwal and Dr. Herbert Vandenberg between July and October of 2006.[3] As stated by Dr. Vandenberg, there is no indication in his

[1] Exh. "A" – Williams Dep. Tr. 31:5-32:4.
[2] Exh. "A" – Williams Dep. Tr. 37:17-38:15.
[3] Exh. "B" – Vandenberg Dep. Tr. pp. 44-45; Exh. "C" – Agarwal Dep. Tr. pp. 25, 36-37.

records that Plaintiff suffered a side-effect from his use of Risperdal or any other medicine during his care.[4]

Plaintiff's expert reports were originally due on February 29, 2016. (Rec. Doc. No. 11). Unable to comply with this deadline, Plaintiff requested and was given an extension until April 29, 2016 (Rec. Doc. No. 13). Still unable to furnish evidence in support of his case, Plaintiff requested an informal, reciprocal extension of the April 29, 2016 deadline to May 31, 2016, to which the Defendants agreed. To date, no expert reports have been furnished.

II. LAW AND ARGUMENT

Summary judgment should be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed R. Civ. P. 56(c). Because the burden of proof at trial is on the Plaintiff, Defendants must identify the elements of the opposing party's claims for which there is an absence of proof. *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 263 (5th Cir. 2002); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Here, as demonstrated *infra*, Defendants lack the evidence required to establish his claims under the LPLA, and therefore Defendants are entitled to judgment as a matter of law.

In Louisiana, suits for injuries caused by medical devices are governed by the Louisiana Products Liability Act ("LPLA"), which is the exclusive theory of liability against product manufacturers for injuries caused by their products. La. Rev. Stat. Ann. § 9:2800.52 (West 2016); *Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1248 (5th Cir. 1997) ("Louisiana law eschews all theories of recovery in this case except those explicitly set forth in the LPLA."). "To maintain a successful products liability action under the LPLA, a plaintiff must establish four

[4] Exh. "B" – Vandenberg Dep. Tr. 47:20-48:1.

elements: (1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product 'unreasonably dangerous;' and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else." *Stahl.,* 283 F.3d at 260-61 (emphasis added); *see also* La. Rev. Stat. Ann. § 9:2800.54(A) (West 2016).

A. Plaintiff's Failure To Provide An Expert To Testify As To Causation Is Fatal To All Of Plaintiff's Claims.

Courts routinely recognize the necessity of expert testimony to prove medical causation in product liability cases. *See Lewis v. Pfizer Pharm. Co.*, 2010 U.S. Dist. LEXIS 99648, at *1 (Sept. 20, 2010) (granting summary judgment where plaintiff failed to provide evidence of medical causation in product liability claims); *Oiler*, 2004 U.S. Dist. LEXIS 2481, at *26 (E.D. La. Feb. 16, 2004)(granting summary judgment on LPLA claims in medical device case because "plaintiff has presented no expert testimony that the type of infection [decedent] contracted could have been caused by a contaminated prosthesis"); *see also Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1252 (11th Cir. 2010). The LPLA expressly provides that a plaintiff must demonstrate "proximate" cause, regardless of their theory of liability. LSA-R.S. 9:2800.54.

And, in cases involving prescription medical products, Plaintiff must present expert evidence that (1) the product is capable of causing the condition alleged (general causation) and (2) that the product caused the Plaintiff's specific injuries (specific causation). *Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1173 (E.D. La. 1997). The failure to produce expert evidence on either of these issues warrants dismissal by summary judgment. *Id.*

Here, there is no medical or scientific evidence on the issue of causation. Therefore, Plaintiff's claims should be dismissed.

B. Even If Evidence Of Causation Exists, Plaintiff Has Produced No Evidence That Risperdal Is Defective Within The Meaning Of The LPLA.

The Louisiana Products Liability Act ("LPLA") sets forth the exclusive theories of recovery for product liability claims, like those of the plaintiff. LSA-R.S. 9:2800.52 (2010); *see also generally*, LSA-R.S. 9:2800.51 *et seq.* (2010). In this case, Plaintiff claims that the drug was unreasonably dangerous in construction or composition, design, lacked adequate warnings, and failed to conform to an express warranty. (Rec. Doc. 1, ¶¶ 16-19, 20-23, 24-27, and 28-31). However, Louisiana law is clear that "defects are not presumed to be present by the mere happening of an accident." *Spott v. Otis Elevator Co.*, 601 So. 2d 1355, 1364 (La. 1992); *see also Grenier v. Medical Engineering Corp.*, 243 F.3d 200, 205 (5th Cir. 2000) ("Louisiana law does not allow a fact finder to presume an unreasonably dangerous design solely from the fact that an injury occurred."). In this case, Plaintiff has adduced no evidence that the product is "defective" within the meaning of the LPLA.

1. Plaintiff's Failure To Submit Expert Evidence Is Fatal To His Claims For Defective Composition And Defective Design.

In order to prove a claim of defective construction or composition under the LPLA, Plaintiff must "demonstrate not only what a manufacturer's specifications or performance standards are for a particular product, but how the product in question materially deviated from those standards so as to render it 'unreasonably dangerous.'" *Morris v. United Servs. Auto. Ass'n*, 756 So. 2d 549, 558 (La. App. 2 Cir. 02/18/00); *see also Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 262-63 (5th Cir. 2002); *Reed v. Biomet Orthopedics, Inc.*, 318 Fed. Appx. 305, 307 (5th Cir. 2009). As stated by the U.S. Fifth Circuit in *Stahl*, "the plaintiff must demonstrate that "at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." *Stahl,* 283 F.3d at 263.

In order to make this showing in a case involving a complex medical product, Plaintiff must produce expert evidence sufficient of raising a genuine issue of material fact. *Zachary v. Dow Corning Corp.,* 884 F.Supp 1061 (M.D. La. 1995) (whether or not medical product was defective in construction or composition was not something that could be determined without expert testimony). Here, Plaintiff has adduced no evidence, fact or expert, in support of his composition defect claim.

Similarly, for claims of defective design, Plaintiff must produce expert evidence demonstrating that a feasible, safer alternative design existed that would have prevented Plaintiff's injury. *McCarthy v. Danek Med., Inc*., 65 F. Supp. 2d 410 (E.D. La. 1999) (defective design claim failed absent expert evidence as to existing alternative design). Here, Plaintiff has offered no reports and provided no evidence in support of his design defect claim.

2. Plaintiff Has No Claim for Failure to Warn.

To maintain a failure-to-warn claim, a plaintiff must demonstrate that "the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product." La. Rev. Stat. § 9:2800.57(A). The characteristic rendering the product unreasonably dangerous because of an inadequate warning must have existed at the time the product left the manufacturer's control, or result from a reasonably anticipated alteration of modification of the product. La. Rev. Stat. § 9:2800.54(C).

Louisiana applies the learned intermediary doctrine to claims arising from the use of prescription drugs. *Zachary v. Dow Corning Corp*., 884 F. Supp. 1061, 1065 (M.D. La. 1995). Under this doctrine, a manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from such prescription drugs. *See Stahl v.*

Novartis Pharmaceuticals Corp., 283 F.3d 254, 265-66, 268 (5th Cir. 2002) (explaining the contours of the learned intermediary doctrine); *see also McCarthy v. Danek Med., Inc*., 65 F. Supp. 2d 410, 413 (E.D. La. 1999) ("Under Louisiana law generally, a manufacturer of medical drugs and devices has no duty to warn the consumer directly of any risks or contraindications associated with its products.").

In order to prevail on a failure-to-warn claim, a plaintiff must therefore show: That the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician; and that this failure to warn the physician was both a cause-in-fact and the proximate cause of the plaintiff's injury. *Stahl,* 283 F.3d at 265-66. An "'[a]dequate warning' means a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made." La. Rev. Stat. § 9:2800.53(9).

In this case, Plaintiff was prescribed Risperdal over a four month period in 2006 by Dr. Rita Agarwal and Dr. Herbert Vandenberg. The testimony of these physicians completely precludes any claim for failure to warn. Plaintiff's prescriber, Rita Agarwal, M.D., testified that she knew of the risks associated with Risperdal®, namely gynecomastia, when she prescribed the drug to the plaintiff:

> Q: All right. And then underneath the various indications and usage there's a section that begins right at the bottom of the page called "Precautions." Do you see that?
>
> A: Yes, sir.
>
> Q: Okay. And then if you flip over to the next page there's a section entitled, "Hyperprolactinemia." . . .

A: Uh-huh (yes). (Witness peruses document.) Okay.

Q: Okay. Does that section indicate to you that risperidone elevates prolactin levels?

A: That's true.

Q: Okay. And it also indicates that the elevation persists during chronic administration. Yes?

A: Yes, sir.

Q: And that section indicates also that conditions such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin elevating compounds. Yes?

A: Yes, sir.

MS. HAYES: Objection.

Q: All right. And that's something that you were aware of back in 2006?

MS. HAYES: Objection.

A: These – All my antipsychotic medication can increase the prolactin level, some more, some less, you know.

Q: Okay. But that was something you knew about Risperdal even back in 2006. Yes?

A: Yes, sir.[5]

Dr. Agarwal also testified that she took the risk of gynecomastia into account when she prescribed Risperdal to the plaintiff:

Q: And the elevation [of prolactin levels] may be more or less, depending on the particular medicine, but it's still something that you're aware of even today?

A: Yes, sir. I mean, from beginning, it started with chloropromazine. It causes gynecomastia, and most of the Dopamine D2 receptor medication, they can do it, you know.

[5] Exh. "C" – Agarwal Dep. Tr. 42:22-44:3.

Q: Okay. So this is something that you've known about from the entire time that you've been using Risperdal. Correct?

A: Yeah, we all know. All the psychiatrists know, yes.

Q: Okay. And it was something that you accounted for in the potential side effects when you were making your risk/benefit decision for Mr. Williams. Yes?

A: That's true.[6]

Plaintiff's second prescriber, Herbert Vandenberg, M.D., also testified that he was aware of the potential association between Risperdal and gynecomastia and accounted for it in his decision making process:

Q. …When you make a decision to prescribe the medicine Risperdal, what are some of the main side effects that you take -- that you account for sort of in your risk-benefit analysis?

A. Weight gain, akathisia.

Q. What is that?

A. Restlessness. Sedation; increased prolactin secondary to breast enlargement; extrapyramidal syndrome, like stiffness.[7]

* * *

Q. Okay. And the risks that you described earlier, including elevated prolactin and gynecomastia, were those risks that you considered when you made the decision to make this prescription in July of 2006?

MS. HAYES: Objection.

A. What you do with that is you measure the risk versus the benefit. Which is more risky right there, the gynecomastia or the family fear of his mother? So I have no problems giving him Risperdal there.

Q. Right. And you were aware of the various side effects that we talked about earlier, including gynecomastia?

[6] Exh. "C" – Agarwal Dep. Tr. 44:8-21.
[7] Exh. "B" – Vandenberg Dep. Tr. 14:11-19.

A. Yes. Yes.[8]

Plaintiff has adduced no testimony from either Dr. Agarwal or Dr. Vandenberg indicating that they were unaware of the alleged association between gynecomastia and Risperdal use. Moreover, Plaintiff has adduced no testimony from either Dr. Agarwal or Dr. Vandenberg indicating that some other warning would have changed their prescribing decision. Indeed, both physicians testified that they stood by their prescribing choice for the Plaintiff and they still routinely use the medicine even today.[9]

3. Plaintiff Has No Claim for Breach of Warranty

For breach of warranty claims, the Plaintiff must put on evidence that express statements were made that "induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue." *Aucoin v. Amneal Pharm., LLC*, No. CIV.A. 11-1275, 2012 WL 2990697, at *10 (E.D. La. July 20, 2012). Here, Plaintiff has submitted no evidence showing any alleged "warranty," much less a warranty that was untrue and/or material in the prescribing physician's decision to use the medicine.

Because no evidence exists showing that the product is defective within the meaning of the LPLA, Plaintiff's claims fail.

B. Plaintiff's Non-LPLA Claims Are Barred By the Exclusivity Provisions of La. Rev. Stat. Ann. § 9:2800.52.

Plaintiff has alleged several claims falling outside the scope of the Louisiana Products Liability Act: negligence (Rec. Doc. 1, at ¶ 32); redhibition (Rec. Doc. 1, at ¶ 36); breach of warranty of fitness for ordinary use (Rec. Doc. 1, at ¶ 40); breach of implied warranty of merchantability and fitness (Rec. Doc. 1, at ¶44); strict liability (Rec. Doc. 1, at ¶ 48); violation of federal regulations (Rec. Doc. 1, at ¶ 52). In Louisiana, suits for injuries caused by products

[8] Exh. "B" – Vandenberg Dep. Tr. 45:6-20.
[9] Exh. "B" – Vandenberg Dep. Tr. 54:3 - 55:8; Exh. "C" – Agarwal Dep. Tr. 44:14 - 45:3.

are governed by the Louisiana Products Liability Act, which is the exclusive theory of liability against product manufacturers for injuries caused by their products. La. Rev. Stat. Ann. § 9:2800.52 (West 2016) ("A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in [the LPLA]"); *see also Stahl v. Novartis Pharm. Corp., 2*83 F.3d 254, 261-62 (5th Cir. 2002); *Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1248 (5th Cir. 1997) ("Louisiana law eschews all theories of recovery in this case except those explicitly set forth in the LPLA."). As this Court has recognized, "**[e]ven though an action under the LPLA is predicated on principles of strict liability, negligence, or warranty, these theories are not available as independent theories of recovery against the manufacturer**." *Watson v. Bayer Healthcare Pharm., Inc.*, Civil Action No. 13-212, 2013 WL 1558328 at *3 (E.D. La. Apr. 11, 2013) citing S*tahl v. Novartis Pharma. Corp*., 283 F.3d 254, 261 (5th Cir.2002) (emphasis added). The LPLA also precludes implied warranty claims in product liability actions under Louisiana law. *See* La. Rev. Stat. Ann. §§9:2800.52, 54 (West 2016); *see also*, e.g., *Grenier v. Medical Eng'g Corp.,* 99 F. Supp. 2d 759, 763 (W.D. La. 2000), *aff'd*, 243 F.3d 200 (5th Cir. 2001) (dismissing, *inter alia*, plaintiff's implied warranty claims).

Courts routinely dismiss product defect claims against manufacturers that do not arise under the theories of liability established in the LPLA. *See, e.g., Stahl*, 283 F.3d at 261-62 (5th Cir. 2002) (stating that negligence is no longer viable as an independent theory of recovery against a manufacturer); *Grenier.*, 99 F.Supp.2d at 763 (holding that plaintiff's claims for strict liability, negligence, breach of warranty of fitness for particular purpose, breach of implied warranty, misrepresentation/fraud, fraud by concealment, false advertising, negligent infliction of emotional distress, common plan to prevent public awareness of breast implant hazards, and

future product failure were not cognizable under the LPLA); *Jefferson*, 106 F.3d at 1251 (affirming dismissal of plaintiff's claims of negligence, fraud by misrepresentation, market share liability, breach of implied warranty of fitness, and civil conspiracy due to exclusivity of the LPLA); *Brown v. R.J. Reynolds Tobacco Co*., 852 F. Supp. 8, 9 (E.D. La. 1994), aff'd, 52 F.3d 524 (5th Cir. 1995) (dismissing plaintiff's claims for fraudulent misrepresentation, concealment, and conspiracy due to the LPLA's exclusivity). Because the LPLA provides the exclusive remedy against the manufacturers for alleged damages arising from use of their products, Plaintiff's claims falling outside the scope of the Act must be dismissed.

III. CONCLUSION

For the foregoing reasons, Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research and Development, LLC respectfully request that the Court grant summary judgment in their favor on all of Plaintiffs' causes of action.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2016, the foregoing pleading was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the court's electronic filing system.

/s/ Douglas J. Moore